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This is the author's manuscript

Original Citation:

Availability:

This version is available <http://hdl.handle.net/2318/140898> since 2020-06-17T11:56:54Z

Published version:

DOI:10.1007/s00592-013-0470-1

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UNIVERSITÀ DEGLI STUDI DI TORINO

This is an author version of the contribution published on:

Questa è la versione dell'autore dell'opera:

Acta Diabetol. 2013 Dec;50(6):873-7. doi: 10.1007/s00592-013-0470-1.

Epub 2013 Mar 23.

The definitive version is available at:

La versione definitiva è disponibile alla URL:

<http://link.springer.com/article/10.1007%2Fs00592-013-0470-1>

Quality of life, impaired vision and social role in people with diabetes. A multicenter observational study.

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Short title: Visual loss in diabetes and quality of life

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ABSTRACT

Diabetic retinopathy may induce visual impairment. We evaluated vision-related quality-of-life in patients with retinopathy and visual acuity $<5/10$ in the better eye using the 25-item National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25). The NEI VFQ-25 was self-administered to 196 patients in 3 Italian centres (A, B and C; n=64, 61 and 71, respectively) dedicated to DR screening and treatment. Patients in the 3 centres did not differ by age, gender, occupation and diabetes duration. Multivariate analysis demonstrated that reduced visual acuity was associated with decreased scores for General Vision, Near Activities, Distance Activities, Visual Specific Social Functioning, Mental Health, Role Difficulties and Dependency, Driving, Colour Vision and Peripheral Vision ($p<0.01$, all). Treatment by photocoagulation was associated with reduced scores in General Health (-8.3; $p=0.002$), General Vision (-7.2; $p=0.001$), Visual Specific Role Difficulties (-8.8; $p=0.015$) and Driving (-13.7; $p=0.003$). Centre affiliation was associated with different scores for General Health, Ocular pain, Distance Activities, Visual Specific Social Functioning and Role Difficulties and Peripheral Vision. Women had higher scores for General Vision ($p=0.015$), Near Activities ($p=0.005$), Distance Activities ($p=0.006$), Visual Specific Social Functioning ($p=0.03$), Visual Specific Mental Health ($p=0.035$) and Colour Vision ($p=0.012$). Diabetic retinopathy and vision loss modify the way people perceive their own ability to function autonomously. More data should be collected to confirm this interpretation and to guide the development of more appropriate settings to improve approach and support to patients.

Abstract word count: 232

KEY WORDS: Quality of life, vision related quality of life, diabetic retinopathy, visual loss.

INTRODUCTION

Diabetic retinopathy (DR) develops in most people with diabetes and may progress to sight-threatening stages in some of them (1). Despite all efforts to achieve good control of blood glucose (2,3) and blood pressure (4) and active screening for sight-threatening DR (5), some patients may suffer serious impairment of their visual function and a consequent decrease in their quality of life (6). Vision plays an important role in the ability of people to process information from their environment and to participate in everyday activities such as reading, working at home or in the office, walking, driving, and interacting with others (7). People with visual impairment may face challenges in completing these activities, which in some cases may lead to depression, social isolation, and difficulties at home, in school, or at work (8). The 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) was developed to measure self-reported, vision-related aspects of health status that are most significant to individuals with chronic eye disease (9,10). In this study we evaluated changes in vision-related quality-of-life in patients with DR and impaired vision using the NEI VFQ-25 in 3 Italian centres dedicated to screening and treatment of DR.

PATIENTS AND METHODS.

A validated Italian version of the NEI VFQ-25 (11) was self-administered, between 2007 and 2010, to 196 consecutive patients with visual acuity $<5/10$ (LogMar 0.3) in the better eye, 64 in Centre A, 61 in Centre B, and 71 in Centre C, on the occasion of routine visits. If the patients had difficulties with reading or literacy problems, they were assisted by a trained operator. The study was performed following all guidelines for experimental investigations required by the Institutional Review Board or Ethics Committee of the institutions to which the authors are affiliated. Informed consent was obtained from the patients and none refused to participate. For each patient we collected age, gender, education, work activity, diabetes type, frequency of screening for diabetic retinopathy, visual acuity, presence of cataract in one or both eyes and laser treatment in progress and /or past. Their main clinical characteristics are shown in Table 1.

Questionnaire

The NEI VFQ-25 includes 25 items that measure vision-targeted health related quality of life (HRQoL) and are grouped into 12 subscales: general health (1 item); general vision (1 item); ocular pain (2 items); difficulty with near-vision activities (3 items); difficulty with distance-vision activities (3 items); limitations of social functioning due to vision (2 items); mental health problems due to vision (4 items), role limitations due to vision (2 items); dependency on others due to vision (3 items); driving difficulties (2 items); difficulty with colour vision (1 item); and difficulty with peripheral vision (1 item). Each subscale is converted to a score between 0 and 100, where higher

scores indicate better vision-specific HRQoL. The composite VFQ-25 score is the mean score of all items, except for the general health item. The questionnaire had been translated into Italian and validated (11)

Centres

All Centres provided informative leaflets and displayed wall-mounted posters on DR for their patients and had flexible appointment policies but differed in many other respects.

One centre is in a city of about 1 million inhabitants and performs screening and photocoagulation within an Internal Medicine Department. The building is 75 years old. Three rooms, 5 physicians and 3 nurses are dedicated to DR screening and laser treatment. This Centre serves diabetes clinics and patients from within and outside the Department. No programme is specifically dedicated to informing patients about DR and its treatment. The second centre is in a town of about 160,000 inhabitants and is located in a small building within the ophthalmic department of a 90 year old main hospital. Every room is dedicated to a specific eye care activity. Patients are informed about DR by the referring diabetologist and looked after by ophthalmic residents. Five ophthalmologists perform DR screening and treatment. The third centre is an academic eye clinic in a town with a population of about 70 000, which has been collaborating with the local diabetes clinic for many years. The hospital is 50 years old but the eye clinic has spacious and bright rooms. Two days a week are dedicated to laser treatment and, before each session, a nurse and an ophthalmologist inform patients about retinopathy screening and how it is administered.

Statistical analysis

Descriptive results are shown as absolute frequencies for categorical data and as mean \pm SD for continuous variables. The chi-square test was used for categorical variables, Analysis of variance (ANOVA) with Bonferroni correction, or Kruskal-Wallis test in the case of non-parametric distribution, were used for continuous variables in order to assess whether significant differences could be detected among the 3 centres.

Multivariate analysis models were fitted: scores from the different subscales of vision-related quality of life were set as dependent variables and age, gender, diabetes type, visual acuity, presence of cataract in one or both eyes, severity of retinopathy (4 categories, ranging from moderate non-proliferative DR with clinically significant macular edema to severe proliferative DR), previous laser treatment and centre affiliation were taken as independent variables. For all tests a p-value of less than 0,05 was considered significant. All analyses were performed with Stata 11.

RESULTS

Patients in the 3 centres did not differ by age, gender, occupation or diabetes duration, but did for schooling, type of diabetes, cataract status, previous laser treatment and frequency of eye control visits (Table 1).

Multivariate analysis demonstrated that impaired Visual Acuity was associated with lower scores in General Vision, Near Activities, Distance Activities, Visual Specific Social Functioning, Visual Specific Mental Health, Visual Specific Role Difficulties, Visual Specific Dependency, Driving, Color Vision and Peripheral Vision ($p<0.01$) (Results not shown).

Previous treatment by laser photocoagulation was associated with lower scores in General Health (-8.3; $p=0.002$), General Vision (-7.2; $p=0.001$), Visual Specific Role Difficulties (-8.8; $p=0.015$) and Driving (-13.7; $p=0.003$) scales.

Centre affiliation was associated with lower scores in General Health (Centre B vs Centre A: -8.5; $p=0.022$) and with differences in Ocular pain, Near-Vision Activities, Distance Activities, Visual Specific Social Functioning, Visual Specific Role Difficulties, Visual Specific Dependency, Color Vision, and Peripheral Vision, the lowest scores being in Centre C and the highest in Centre B (Table 2).

Women had higher scores for General Vision ($p=0.015$), Near Activities ($p=0.005$), Distance Activities ($p=0.006$), Visual Specific Social Functioning ($p=0.03$), Visual Specific Mental Health ($p=0.035$) and Colour Vision ($p=0.012$).

DISCUSSION

The NEI VFQ-25 was developed from focus groups with patients representing a diverse range of visual conditions, with the aim of developing a scale that could be generalized to all patients with vision impairments, regardless of the cause (9,10). The Los Angeles Latino Eye Study (LALES) is one prominent example where the impact of vision loss on HRQoL was assessed over four years in a population cohort (8). The study assessed different conditions, including glaucoma, retinopathy and age-related macular degeneration and some of the data were focused on the changes experienced by people with diabetic retinopathy.

In this study, multivariate analysis demonstrated that reduced visual acuity in patients with DR was associated with decreased quality of life due to impaired General Vision, Near Activities, Distance Activities, Visual Specific Social Functioning, Visual Specific Mental Health, Visual Specific Role Difficulties, Visual Specific Dependency, Driving, Colour Vision and Peripheral Vision, and that the relevant scores worsened significantly with decreasing visual function. The dimensions influenced by the presence of diabetic retinopathy detect fragility in social role in addition to dependency in everyday life. Women had better results in some of the subscales, independently of the other variables considered, but this result is difficult to interpret on the basis of the data available for this study. There were also centre-specific differences with patients in one centre

faring better scores than in the other two. The patients in the 3 centres had similar age, gender, occupation, diabetes duration and treatment and, although there were some differences in schooling, prevalence of cataract and visual acuity, these did not appear to explain the differences in quality of life. Different resources devoted to informing patients about DR, its treatment and possible consequences did not appear to be associated with quality of life in the patients.

Previous laser treatment was associated with further worsening in some of the indicators, especially those related to general health and vision and everyday activities, such as driving. Possibly, this is a consequence of more advanced DR severity, which in turn is associated with increased morbidity for cardiovascular and other causes (12). In one study comparing visually impaired individuals with and without DM, those with DM reported poorer general health, less satisfaction with physical health, and more negative feelings generally (13).

A study published in 2007 suggested that the VFQ-25 score is decreased to a similar extent in patients with type 2 diabetes and DR and patients with age-related macular degeneration and that in both conditions it is reduced more than in patients with type 1 diabetes and DR, glaucoma or cataract (14). Hariprasad et al. also reported that people with type 2 diabetes and diabetic macular edema have scores similar to patients with age-related macular degeneration (15). This study confirms that patients with visual impairment due to DR experience discomfort in everyday life and lose autonomy in day-to-day functioning, with loss of ability to perform specific tasks.

The NEI VFQ-25 had been used in previous clinical studies (16) demonstrating consistency and validity to assess the impact of retinopathy on the lives of people with diabetes. Further evidence supports the validity and reliability of the NEI VFQ-25 to measure quality of life in Diabetic Macular Edema (17). Marella et al. questioned the overall psychometric validity of the questionnaire, suggesting that the items grouped under visual functioning and socio-emotional traits are its most valid constructs (18). However, despite these limitations, the questionnaire was found superior to other tools in assessing vision related quality of life (19) and it was the visual functioning and socioemotional traits that came out as most relevant in this survey.

Limitations of this study include a limited sample size, centre selection and the absence of exclusion criteria for depression. The latter may be a confounder in the perception of quality of life regardless of the presence/absence of retinopathy and its severity. No subanalysis was carried out to differentiate between Type 2 and Type 1 diabetes, but the aim was to assess the impact of retinopathy in the life of a person with diabetes.

Studies exploring psychological adjustment in individuals with diabetes and visual impairment (20) showed that even people with mild DR express feelings of uncertainty and vulnerability at the prospect of vision loss. Similarly to other industrialized countries, the social security system in Italy provides free access to eye care services, such as screening, assessment and treatment for diabetic

retinopathy, although in many instances visits are carried out on a fee-for-service basis. However, health care systems too often underestimate the problems that may arise in the quality of life of patients (21), especially in view of the tendency of diabetes to associate with depression (22). The projected increasing prevalence of STDR and visual impairment (23) and the associated reduction in functional status and independence, will greatly increase the resulting burden of this complication of diabetes.

ACKNOWLEDGEMENTS

No financial support was received for this study.

Conflict of Interest: None

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Table 1 - Data of patients (absolute frequencies of the different categories or mean \pm SD in case of continuous variables) Significance is based on chi-square tests among the three centres for categorical variables and ANOVA test for continuous variables.

	Total (n=196)	Centre A (n=64)	Centre B (n=61)	Centre C (n=71)	Significance
Gender (M/F)	105/91	35/29	27/34	43/28	NS
Age (years)	69.7 \pm 6.6	70.7 \pm 6.9	68.9 \pm 7.1	69.3 \pm 5.8	NS
Known duration of diabetes	16.3 \pm 6.6	17.2 \pm 6.9	16.0 \pm 7.9	15.9 \pm 5.3	NS
Schooling ^a (N/P/M/H/U)	5/126/45/16/4	5/39/18/2/0	0/40/12/6/3	0/47/15/8/1	<i>p=0.020</i>
Occupation ^b (H/R/B/W/T/C)	9/177/4/3/1/2	2/61/0/1/0/0	4/49/3/2/1/2	3/67/1/0/0/0	NS
Diabetes type (Type 1/Type 2)	11/185	4/60	7/54	0/71	<i>p=0.016</i>
Glucose-lowering treatment ^c (D/H/H+I/I)	1/31/44/120	0/15/12/37	0/8/15/38	1/8/17/45	NS
Visual Acuity ($\leq 1/ >1\leq 2/ >2\leq 3/ >3\leq 4/ >4$)	13/24/45/40/74	10/6/21/13/14	1/5/11/13/31	2/13/13/14/29	<i>p=0.002</i>
Cataract (No/1 eye/ both eyes/IOL/NA)	74/29/62/26/5	35/6/15/5/3	17/14/14/16/0	22/9/33/5/2	<i>p<0.000</i>
Retinopathy ^d (NPDR/PREP/PDR/DME)	26/12/42/116	25/7/10/22	0/3/0/58	1/2/32/36	<i>p<0.000</i>
Laser ^e (N/Y/M/NA)	56/39/97/4	13/5/44/2	15/16/28/2	28/18/25/0	<i>p=0.001</i>
Last eye check (Last month/Last 6 months/Last Year)	76/100/20	24/27/13	11/47/3	41/26/4	<i>p<0.000</i>

^aN = No formal education, P = Primary school, M = Middle school, H = High school, U = University degree

^bH = Housewife, R = Retired, B = Blue collar worker, W = White collar worker, T = Teacher, C = Craftsman

^cD=Diet, H=Hypoglycemic, I=Insulin, N = missing

^dNPDR = mild to moderate non proliferative DR; PREP = severe non proliferative DR (pre-proliferative); PDR = proliferative DR; DME = diabetic macular edema

^eN=Never, Y= in the last Year, M= in the last Month, NA = Not Available

Table 2 – NEI VFQ-25 Results (mean \pm SD). Significance levels are based on Kruskal-Wallis test among the three centres.

	Total (n=196)	Centre A (n=64)	Centre B (n=61)	Centre C (n=71)	Significance
GH - general health	51.0 \pm 15.8	53.6 \pm 17.5	49.5 \pm 13.2	49.9 \pm 16.1	NS
GV - general vision	47.7 \pm 14.7	46.6 \pm 13.2	50.5 \pm 15.5	46.3 \pm 15.1	NS
OP - ocular pain	81.3 \pm 17.9	85.4 \pm 16.3	85.7 \pm 16.9	73.9 \pm 18.0	<i>p</i> <0.005
NA - near-vision activities	59.1 \pm 25.3	55.4 \pm 26.7	67.5 \pm 24.3	55.2 \pm 23.4	<i>p</i> =0.009
DA - distance-vision activities	70.4 \pm 24.3	73.5 \pm 21.4	79.1 \pm 21.2	60.2 \pm 25.8	<i>p</i> <0.005
VSSF - Visual Specific Social Functioning	77.8 \pm 22.8	78.6 \pm 23.5	88.1 \pm 16.8	68.3 \pm 22.9	<i>p</i> <0.005
VSMH - Visual Specific Mental Health	55.8 \pm 25.1	56.8 \pm 22.8	61.6 \pm 24.2	50.0 \pm 26.7	NS
VSRD - Visual Specific Role Difficulties	65.0 \pm 25.5	64.3 \pm 28.8	74.7 \pm 22.6	57.3 \pm 22.2	<i>p</i> <0.005
VSD - Visual Specific Dependency	63.4 \pm 29.3	62.1 \pm 30.8	75.3 \pm 27.0	54.5 \pm 26.5	<i>p</i> <0.005
D - Driving	47.8 \pm 28.1	49.4 \pm 23.5	49.0 \pm 36.5	45.3 \pm 23.5	NS
CV - Color Vision	71.8 \pm 28.1	66.9 \pm 28.9	83.6 \pm 24.9	65.9 \pm 27.3	<i>p</i> <0.005
PV - Peripheral Vision	73.3 \pm 23.9	73.7 \pm 23.5	83.6 \pm 19.8	64.17 \pm 23.9	<i>p</i> <0.005